## **DEPARTMENT OF HEALTH & HUMAN SERVICES**



Public Health Service

Food and Drug Administration Minneapolis District 240 Hennepin Avenue Minneapolis MN 55401-1999 Telephone: 612-334-4100

January 16, 2002

## WARNING LETTER

## CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 02 - 21

David W. Goodrich Owner Goodrich Farms, LLP 1947 – 220<sup>th</sup> Avenue Deer Park, Wisconsin 54007

Dear Mr. Goodrich:

An investigation at your dairy farm located at Deer Park, WI, conducted by our investigators on January 2, 2002, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about October 26, 2001, you sold a cow (identified as cow #485 in your records) for slaughter as human food to USDA analysis of tissue samples collected from that animal identified the presence of penicillin at 1.11 ppm in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. As noted in form FDA-483 issued to you on January 2, 2002, you did not follow the labeled withdrawal time of 10 days after treating your cow #485 with penicillin. Foods from animals

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held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You are adulterating the penicillin drug that your firm uses on cows within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your reply should be addressed to Compliance Officer Timothy G. Philips at the address on the letterhead.

Sincerely,

David R. Yos¶

Acting Director

Minneapolis District

TGP/ccl